

FORM PTO 1390  
(REV 11-98)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

HAMMON-002

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

09/936721

INTERNATIONAL APPLICATION NO.  
PCT/EP00/02407 ✓INTERNATIONAL FILING DATES  
17 March 2000 ✓PRIORITY DATE CLAIMED  
18 March 1999 ✓

TITLE OF INVENTION ARTIFICIAL URINARY DIVERSION SYSTEM

APPLICANT(S)  
FOR DO/EO/US

Helmut WASSERMANN, et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to promptly begin national examination procedures (35 U.S.C. 371 (f)).
4. ☒ The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
  - a. ☐ is attached hereto (required only if not transmitted by the International Bureau).
  - b. ☒ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). (Unexecuted)
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

**Items 11. to 16. below concern document(s) or information included:**

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98. w/PTO-1449, \_\_\_ references
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 & 3.31 is included.
13. ☐ A **FIRST** preliminary amendment.  
☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:

Copy of International Application as published (In German)  
Copy of International Search Report (In German)

**EXPRESS MAIL LABEL NO. EL804522344US****DATE:** September 17, 2001

T06T2T 12292560

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17. ☒ The following fees are submitted:**BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):**

- ☐ Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO . . . . . \$1,000.00
- ☒ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO . . . . . \$860.00
- ☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO . . . . . \$710.00
- ☐ International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) . . . . . \$690.00
- ☐ International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) . . . . . \$100.00

**ENTER APPROPRIATE BASIC FEE AMOUNT =**

860.00

Surcharge of \$130.00 for furnishing the oath or declaration later than

☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	29 - 20	9	x \$18.00	162.00	
Independent claims	1 - 3 =	1	x \$80.00		
MULTIPLE DEPENDENT CLAIM(s) (if applicable)			+ \$270.00		

**TOTAL OF ABOVE CALCULATIONS =**

1,022.00

☒ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.

-511.00

**SUBTOTAL =**

511.00

Processing fee of \$130.00 for furnishing the English translation later than

☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (f)). +

130.00

**TOTAL NATIONAL FEE =**

641.00

Fee for recording the enclosed assignment (37 CFR 1.21 (h)). Assignment must be accompanied by appropriate cover sheet (37 CFR 3.28, 3.31) +

( \$40.00 per property).

**TOTAL FEES ENCLOSED =**

641.00

Amount to be:  
Refunded

Charged

- a. ☐ A check in the amount of \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 12-1095 in the amount of \$ 641.00 to cover the above fees. A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to my Deposit Account No. 12-1095 . A duplicate copy of this sheet is enclosed.

**NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.**

SEND ALL CORRESPONDENCE TO:

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Description

ARTIFICIAL URINARY DIVERSION SYSTEM

5

The present invention relates to an artificial urinary diversion system according to the generic term of claim 1.

10 Among patients with urinary bladder disorder there is a plurality of findings, which require the removal of the own bladder. In this situation, a urinary diversion, by producing different sorts of reservoirs, is required. So-called wet diversions are distinguished, with direct urinary diversion via the ureters, which are implanted into the abdominal wall, or by insertion of a neutralized part of the intestine, in which the ureters are implanted and which is for its part implanted into the abdominal wall.

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15 In both cases the urine is collected in a urine bag, which is stuck on the orifice.

20 Alternatively, the ureters are implanted into the rectum or - more and more in the past years - into replacement bladders, which are made of neutralized parts of the intestine.

25 These replacement bladders are either connected with the endogenous urethra or they are conducted out by creating an appropriate self-preserving occlusion mechanism at the abdominal skin, for example in the navel region.

30 Typical indicators for a replacement of the endogenous urinary bladder are advanced tumors at the urinary bladder, but there are also malformations, bladder impairments due to inflammation, as well as functional obstructions, such as for

example obstructions by urinating, or development of bladder atrophies among paraplegic people.

Thus, it is the object of the present invention to create  
5 an artificial urinary diversion system, which is adaptable to the different shapings of different persons and which shows the largest possible filling volume.

Further, it is an object of the present invention, that  
10 the artificial urinary diversion systems can be created such adaptable, without previous direct or indirect determination of the potentially available volume for said system that an as effective as possible determination and utilization during the surgical phase of the volume available in the patient is facilitated.

These objects are solved with the features of claim 1.

According to the application, the second area, which is  
20 arranged between the first and the third area, shows a cross-sectional surface that is smaller than the cross-sectional surface of the third area. By this it will be achieved, that a shape is provided, which can be adapted to almost any patient, and particularly, it is achieved that the largest possible  
25 filling volume can be provided, namely by simultaneous observance of the medical preconditions, such as for example the arteries and the intestine that pass after the operation laterally to the second area and on which no pressure must be put on. Attention must be paid to the fact that, with a person  
30 who is standing erect, the third area is arranged above the second and the first area. For example, if perhaps the first area shows a larger cross-sectional surface than the second area, it is also achieved that a so-called constriction will be provided in the second area, which is necessary for the  
35 bypassing arteries and/or the intestine and the kidneys, and

that a positional fixing with the first area is for example possible at the pubic bone (Symphysis Pubica).

Further advantageous embodiments of the following invention are subject matter of the sub-claims.

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15  
10 If, according to claim 2, the first, the second and the third area are modularly compounded or rendered modularly compoundable and if it has been paid attention to the fact that the respective transition surfaces between the individual areas are coordinated in a way, that a continuous transition is resulting, the advantage will be achieved that, according to the respective spatial condition of the patient, the individual areas of the urinary diversion system can be compounded and thus, it will be possible to take optimally account of the anatomical conditions of the patient.

20  
25 If, according to claim 4, a fluid guidance is provided, which extends from the urinary bladder to the outlet in the first area, this corresponds to a large extent to the natural anatomy, which means, that among a person who is standing erect, the lowest, first area can be connected directly with the existing urethra, without using additional connection elements between the urethra and the outlet in the first area, which could possibly cause further medical complications.

30  
35 If, according to claim 5, an actor or an actuator or a pump is provided in the third area, there is no need to provide an external pump, and, in view of the shaping, the first and the second area are not negatively influenced. Furthermore, with the advantageous embodiment that an actuator or a pump are provided in the third area, it is taken account to the fact that said third area, which is optimally embodied, is most likely to have the most space for the integration of a pump without extremely or negatively influencing the shaping.

If, according to claim 6, the pump is formed as a telescope device, the advantage that almost the total volume of the third area can be used for filling the contained urinary bladder can be achieved. Laboratory experiments have already shown that almost the total urinary bladder can be emptied with a telescope device, without leaving any sediment in the urinary bladder.

If, according to claim 7, the pump is formed as a lever pump, the advantage is achieved that no complex mechanics is integrated, such as for example for the use of a telescope device in the third area.

If, according to claim 8, the pump is formed as a screw pump, also the advantage, that almost the total volume of the third area can be used for the urinary bladder, is achieved. In addition, by using a screw pump, the advantage is given, that said screw pump pulverizes possible smaller urine crystals, so that these pulverized crystals can also be passed through a stenotic urethra.

If, according to claim 9, additionally a screw pump is arranged in a way, that it may possibly be displaced laterally to the fluid tube or duct, the advantage can be achieved, that an inlet and a lavage of the artificial urinary diversion system can be caused unproblematically, as the fluid tube will be opened by moving the screw. This practicability concerning the inlet and the lavage of the artificial urinary diversion system is for example very important in the field of spectroscopic examinations.

If, according to claim 10, a sphincter mechanism is preferably provided in the first area, the advantage is achieved, that almost a total control of the urinary

continency is possible. The control of the sphincter mechanism can, for example, also be initiated externally.

5 If, in addition, according to claim 11, a control system is provided, which regulates the sphincter mechanism, said control system, which is additionally able to assume further procedures, can for example also regulate the opening and the closing of the sphincter.

10 If, according to claim 12, a sensor system is provided that controls the filling level of the urinary bladder, the person concerned will be given a high degree of safety by using the artificial urinary bladders. This means that the person concerned does not have to void the urinary bladder  
15 regularly and in short intervals but said person can integrate in the everyday life in the usual way. If either a sound signal or a seismical signal, which will be produced at a certain filling level of the bladder, is sent to the concerned person, said person can move normally in the everyday life.  
20 However, it should be paid attention to the fact, that at least a security regulation is installed in the sensor system, which means, if a certain period of, for example 8 to 12 hours, is exceeded, it should be signaled to the person to void the bladder, independent from the filling level of said  
25 bladder. Furthermore, when controlling the filling level of the artificial bladder a security can be given, which is oriented at the physiological marginal conditions. By this it will be achieved that the artificial urinary diversion system operates similar to the function of the natural urinary  
30 bladder. This means, that with said urinary diversion system it will be achieved that, similar to the natural process, first the body signals the person that the urinary bladder should be emptied, then the bladder will be opened, the urine will be pressed out or squeezed and the bladder will be closed  
35 again.

If, according to claim 13, the sensor system will be controlled by the nerves responsible for the urinary bladder, an almost natural feeling will be given to the concerned person with this neurological solution, which means, an exogenous signal, such as for example produced by a sound signal or a seismical signal will thus not be necessary.

If, according to claim 14, a power supply is additionally provided in the urinary diversion system, a compact urinary diversion device can be provided, which can for example first be integrated in the artificial urinary diversion system. However, it is pointed out that the power supply can also be arranged separately, near the urinary diversion system in the patient, if, for reasons of space, a third area must be used, which does not allow an additional power supply.

If, according to claim 15, an external recharge device will make the power supply, the advantage is achieved, that the urinary diversion system can be almost lifelong provided with power. The charging of the counterpart of the external recharge device can be made by the adapted counterpart, which is charging wireless transcutaneously at an adapted main support place, which is implanted subcutaneously.

A simple power transfer can for example be achieved by the fact, that the recharge device cooperates inductively with the counterpart, with power being for example transferred inductively with frequencies tolerated by the body, for example 30 kHz.

If, according to claim 17, the power supply is made by primary batteries, which are integrated into the urinary diversion device, said urinary diversion device will work



without any continuing maintenance and the person concerned does not have to worry about the power supply.

It is also pointed out that, in case of need, for example the power for the actor system and/or the sensor system can be transferred wireless transcutaneously by placing a suitable transfer device onto the skin. However, it is hereby also necessary that the controlling and providing can also be executed by primary batteries as an additional power source. It is also possible that the total control and sensor system can be interrogated and started external telemetrically.

If, according to claim 18, additionally an actor system is integrated into the urinary diversion device, once again a completely independent system is provided, which only needs to be connected at the inlets or outlets with functional structures of the patient's urinary diversion system and which can be implanted as one compact part.

If, according to claim 19, the third area is constructed bipartite or in two-part form with, dependent on the filling level of the urinary bladder, one part being able to move away from the other part, it is for example possible to flexibly adjust the size of the urinary bladder and the filling level, in accordance with the requirements.

If, according to claim 20, the urinary diversion device shows two inlets in the third area, so that each ureter can be connected with the artificial urinary diversion system, it is thus not necessary to possibly provide a further separate additional element, for example in Y-shape, which can be used, if it is advantageous that the urinary diversion device does only have one inlet.

By providing one or more anti-reflux valves in the third area, in accordance with claim 21, it can be achieved that a reflux of the urine into the kidney is stopped. This also prevents a possible ascent of bacteria from the bladder up to the kidney.

If, according to claim 22, a fixing element is provided, it is easy to arrange and fix it in the human body.

If, according to claim 23, the fixing element is connected with the urinary diversion device via a dovetail joint, a tight or leak-proof connection has been constructed and the fixing element can be kept in the body, in order to be later connected at the right place with the urinary diversion device.

If, according to claim 24, the fixing element is moveably fixed via a guidance system, the urinary diversion device can, according to the anatomy of the person concerned, optimally be arranged and fixed. If furthermore the guide-rail system is integrated into the third area, there are no rails available that are protruding the third area, which could possibly influence the arranging in the human body or cause any functional or spatial inconvenience.

If, according to claim 25, the fixing element shows a splay or expanding element, which for example widens after implanting into the guide rails, a simple connection possibility is given, with especially guarantying a particular compatibility by the complete integration of the splay element into the fixing element.

If, according to claim 26, the fixing element is formed with biocompatible material, such as silicone, a well-tolerated material is given, but also the elasticity of the

silicone and others are taken into account due to the splay movements of the splay element.

Further preferred embodiments of the present invention  
5 are subject matter of the remaining sub claims.

Referring to the following drawings, said artificial urinary diversion system will be described in detail on the basis of a preferred embodiment.

10 Fig. 1 illustrates a schematic diagram of said artificial urinary diversion system;

15 Fig. 2 is a sectional drawing among the intersection line II -II;

Fig. 3 illustrates, in accordance with Fig. 1, a top view of said urinary diversion system;

20 Fig. 4 illustrates a bottom view of said urinary diversion system;

Fig. 5 is, in accordance with Fig. 1, said urinary diversion system with separated single areas;

25 Fig. 6 is a sectional view of the arranging of the urinary diversion system;

Fig. 7 is a front view of said urinary diversion system;

30 Fig. 8 is a top view of a body section regarding intersection VII - VII;

35 Fig. 9 illustrates a diagram, which shows the one executed polynomial function of 6<sup>th</sup> degree regarding

the top surface outline of said urinary diversion system in accordance with Fig. 1;

Fig. 10 is a diagram, which shows the top-view silhouette of said urinary diversion system in accordance with Fig. 1, relating to the mentioned polynomial function of 6<sup>th</sup> degree;

Fig. 11 is an embodiment of the fixing element;

The advantageous embodiment of said urinary diversion system explained in Fig. 1 includes a first area A, a second area B and a third area C, with the cross-sectional surfaces (illustrated hatched) that are perpendicular to the axial alignment of the urinary diversion device of the first, second and the third area, being so constructed, that the cross-sectional surface Q1 of the first area A is larger than the cross-sectional surface Q2 of the second area B and the cross-sectional surface Q3 of the third area C is in each case larger than the cross-sectional surface of the first and the second area. In addition, the first area A shows an outlet 3 and the third area C shows two inlets 5 for the urethras, which come from the respective kidneys.

The first area A of said urinary diversion system shows at its bottom surface 7 an increasing area D, with the shaping possibly being linear, arched, concave or convex, dependent on the patient's anatomic conditions for the urinary diversion system. In Fig. 1 it is clearly visible that the second area B, which is arranged between the first and the third area, is to be regarded as a constriction, with arteries being lead by laterally to its surfaces 9. The third area C, which comprises a urinary bladder, is shaped voluminously enough to allow a filling as large as possible. The two inlets for the renal urethra are provided at the front side of the third area.

Fig. 2 illustrates a laterally sectional view according to intersection II - II. With this sectional view it is clearly visible that the urinary diversion device 1 presented in Fig. 2 shows the top-side of a first outline K1. Here, in contrast to Fig. 1, the elevation of the second area B to the bottom surface 7 of the first area A is more clearly to see. In this embodiment, a curved or curvilinear elevation is shown. Said curved elevation serves to be brought into contact for example with the pubic bone and makes thus a positional fixing possible. It is also visible in Fig. 2 that below the third area so-called guide rails 13 are provided, in which a fixing element (not shown) can be inserted. At this point, special attention shall be drawn to the fact that a protruding of the guide rails may, for example, be avoided by complete integration into the third area.

Fig. 3 illustrates a top view of said urinary diversion system 1 and a second outline K2 in accordance with Fig. 1, with the constriction caused by the second area B being clearly visible, with the arteries being possible to be lead by laterally of the side surfaces 9. The relative proportions, which are shown between the first, the second and the third area, are also clearly visible.

Fig. 4 shows a bottom view of said urinary diversion system 1. The provided guide rails 13 for the fixing element are clearly indicated.

Fig. 5 illustrates said urinary diversion system 1, with its individual areas, i. e. first, second and third area, illustrated separately.

At this point it shall be noted that the division or sectioning into a first area, a second area and a third area

describes a preferred embodiment. Said urinary diversion system can also be provided with only two areas or as an integral entity. On the other hand, also more than three areas, which can be divided separately, are imaginable, with  
5 more areas of the increased adapting variation being taken into account.

Fig. 6 illustrates for example the arranging of said urinary diversion system. The first area A borders on the  
10 pubic bone, with the fixing element, which is moveably includable in the guide rails, being fixed for example at the respective places in the abdominal cavity.

Fig. 7 shows a front view for further illustration of the  
15 arranging of said urinary diversion system.

Fig. 8 is a top view, with the body section being above the section of said urinary diversion system.

Fig. 9 is for example a fit curve of the polynomial form  
20  $f(x) = a_6x^6 + a_5x^5 + a_4x^4 + a_3x^3 + a_2x^2 + a_1x + a$ , i. e. a polynomial of 6<sup>th</sup> degree, which has been adapted to the first outline. The parameters used for this adapting are  $a_6 = -9 \cdot 10^6$ ;  $a_5 = 0,006$ ;  $a_4 = -0,014$ ;  $a_3 = 0,1638$ ;  $a_2 = -0,9319$ ;  $a_1 = 2,6778$   
25 and  $a = 0,8452$ . However, it turned out that within a domain of  $0 \leq X \leq 22$  the coefficients  $a_1$  to  $a_6$  in the domains  $0 < A < 2$ ;  $0 < a_1 < 8$ ;  $-2 < a_2 < 0$ ;  $0 < a_3 < 1$ ;  $-0,1 < a_4 < 0$ ;  $0 < a_5 < 0,003$  and  $-0,00001 < a_6 < 0$  within a domain of  $0 < x < 22$  can be taken.

Fig. 10 illustrates a top view of the half of a second  
30 outline, which has also been approximated with a polynomial of 6<sup>th</sup> degree. The parameters used for this were  $a_6 = 1 \cdot 10^{-5}$ ;  $a_5 = 0,008$ ;  $a_4 = -0,0198$ ;  $a_3 = 0,221$ ;  $a_2 = -1,2703$ ;  $a_1 = 3,9521$  and  $A = 1,2557$ . It has also turned out that these coefficients can

also be taken in the domains  $0 < A < 2$ ;  $0 < a_1 < 8$ ;  $-2 < a_2 < 0$ ;  $0 < a_3 < 1$ ;  $-0,1 < a_4 < 0$ ;  $0 < a_5 < 0,003$ ; and  $-0,00001 < a_6 < 0$  within a domain of  $0 < x < 22$ , for adapting the respective second outline. To illustrate that Fig. 10 is a top view, the first outline and the fitted curve have been reflected at  $y = 0$  at the x-axis of the diagram.

Fig. 11 illustrates a fixing element 15 with a front area F, which can be introduced into the guide rails of said urinary diversion system, and an end area E, which can, for example be pressed by hand.

Inside of said fixing element 15 there is a splay element (illustrated dashed), which is, due to the upright side surfaces 19A to 19D, for example taken along with the elastically formed fixing element 15 so that, for example, when impacting on the end area, the arms of the splay element 17 in the front area do also move towards each other and take the elastic material of the fixing element 15 with them.

Thus, the fixing element 15 can be narrowed in a way, that it can be included between the two guide rails 13. After introduction, the fixing element 15 will be released, so that, due to the elasticity of fixing element 15 the front area F will be re-given its original shape and a press fit/ tight fit may be achieved with the side surfaces of the guide rails. If now the fixing element 15 shall be moved within the guide rail 13, it is only necessary to re-press or re-contract the end area E, in order to open the press fit of the side surfaces of the front area F. The slots or openings 21 in the fixing element 13 serve for being tightly lead by the guide rails when the position of the fixing element might be re-aligned.

Thus, with this fixing element 15 said urinary diversion device can be arranged suitably before its final arranging and the fixing element can be fixed at the corresponding position in the abdominal cavity.

5

Due to this additional provision, which is providing a fixing element that is separately to the urinary diversion system, it is also possible to pre-fix the fixing element at places difficult to access for fixing a fixing element and to  
10 introduce it then into the urinary diversion device.

Instead of the screw pump, the pump using a telescope device and the lever pump all further sorts of pumps are  
15 imaginable for squeezing the urine, particularly a membrane pump or a gear pump.

The cross-sectional surfaces Q1, Q2 and Q3 can be  
20 different geometrical surfaces, such as quadratic, rectangular, trapezoidal, round, oval, elliptical or any other combination.



IPER Annex

ART 34 AMDT

Main Claim

5

1. Artificial urinary diversion device consisting of at least one first area with at least one outlet, one second area and one third area with at least one inlet, and which shows in the second and/or third area a urinary bladder,

10

characterized in that

the second area (B) is arranged between the first and the third area (A,C) and one of the cross-sectional surfaces (Q1,Q2) of the first and/or second area (A,B), perpendicular to the axial alignment of the urinary diversion device, are smaller than the cross-sectional surface (Q3) of the third area,

15

20

and one of the cross-sectional surfaces (Q1) of the first area (A) being larger than one of the cross-sectional surfaces (Q2) of the second area (B).

25

2. Urinary diversion device according to claim 1, characterized in that the first, the second and the third area (A,B,C) can be compounded modularly, with each transition area defining a basic area, permitting a continuous transition of the urinary diversion system's surfaces.

30

3. Urinary diversion device according to claim 1 or 2, characterized in that a fluid-guidance is provided, which extends from the urinary bladder preferably from the third area (C) to the second area (B) via the first area (A).

35

4. Urinary diversion system according to one of the claims 1 to 3, characterized in that an actor or actuator, preferably a pump, preferably in the third area, is provided.
- 5
5. Urinary diversion device according to claim 4, characterized in that the pump is a telescope device.
6. Urinary diversion device according to claim 4, characterized in that the pump is a lever pump constructed with two chambers.
- 10
7. Urinary diversion device according to claim 4, characterized in that the pump is a screw pump, which is preferably arranged in the first area.
- 15
8. Urinary diversion device according to claim 7, characterized in that one of the screws can be moved laterally.
- 20
9. Urinary diversion device according to one of the claims 1 to 8, characterized in that a sphincter mechanism is provided, which is preferably arranged in the first area.
- 25
10. Urinary diversion device according to one of the claims 1 to 9, characterized in that a control is provided, which preferably controls the sphincter mechanism.
- 30
11. Urinary diversion device according to one of the claims 1 to 10, characterized in that a sensor system is provided, which monitors the filling level of the urinary bladder and preferably produces a sound signal or a seismical signal when reaching a certain filling level of the bladder.

12. Urinary diversion device according to claim 11 characterized in that the nerves responsible for the natural urinary bladder control the sensor system.

5 13. Urinary diversion device according to one of the claims 1 to 12, characterized in that a power supply is provided.

10 14. Urinary diversion device according to one of the claims 1 to 13, characterized in that an external recharge device, which cooperates with a counterpart that is connected with the urinary diversion device, makes the power supply.

15 15. Urinary diversion device according to claim 14, characterized in that the recharge device cooperates inductively with the counterpart.

20 16. Urinary diversion device according to claim 13 characterized in that said power supply is made by primary batteries that are integrated into the urinary diversion device.

25 17. Urinary diversion device according to one of the claims 1 to 16, characterized in that an actor system is provided, which executes the pressing out or squeezing of the urine.

30 18. Urinary diversion device according to one of the claims 1 to 17, characterized in that a bipartite or two-part fluidic part is provided in the third area and, depending on the filling level, one part is able to move away from the other part.

35 19. Urinary diversion device according to one of the claims 1 to 18, characterized in that the third area shows one or two inlets.

20. Urinary diversion device according to one of the claims 1 to 19, characterized in that one or two anti-reflux valves are provided, which are preferably arranged in the third area.

5

21. Urinary diversion device according to one of the claims 1 to 20, characterized in that a fixing element is provided.

22. Urinary diversion device according to claim 21, characterized in that the fixing element is connected with the urinary diversion device via a dovetail joint.

10

23. Urinary diversion device according to claim 21 or 22, characterized by a guide-rail system, in which the fixing element can be moveably included and locked at a suitable position, and the guide-rail system being preferably integrated into the third area.

15

24. Urinary diversion device according to one of the claims 21 to 23 characterized in that the fixing element comprises a splay or expanding element, which is preferably totally included.

20

25. Urinary diversion device according to claim 24, characterized in that the fixing element is made of biocompatible, elastic material, preferably silicone.

25

26. Urinary diversion device according to one of the claims 1 to 25, characterized in that, among a first outline, the shape of the urinary diversion device corresponds to a polynomial function of 6<sup>th</sup> degree

30

$$F(x) = A + a_1x + a_2x^2 + a_3x^3 + a_4x^4 + a_5x^5 + a_6x^6$$

with the coefficients in the domains  $0 < A < 2$ ;  $0 < a_1 < 8$ ;  $-2 < a_2 < 0$ ;  $0 < a_3 < 1$ ;  $-0,1 < a_4 < 0$ ;  $0 < a_5 < 0,003$ ; and  $-0,00001 < a_6 < 0$  within a domain of  $0 < x < 22$ .

- 5 27. Urinary diversion device according to claims 1 to 26, characterized in that, among a second outline, the shape of the urinary diversion device corresponds to a polynomial function of 6<sup>th</sup> degree,

10

$$F(x) = A + a_1x + a_2x^2 + a_3x^3 + a_4x^4 + a_5x^5 + a_6x^6$$

with the coefficients in the domains  $0 < A < 2$ ;  $0 < a_1 < 8$ ;  $-2 < a_2 < 0$ ;  $0 < a_3 < 1$ ;  $-0,1 < a_4 < 0$ ;  $0 < a_5 < 0,003$ ; and  $-0,00001 < a_6 < 0$  within a domain of  $0 < x < 22$ .

15

28. Urinary diversion device according to one of the claims 1 to 27, characterized in that the first, the second and the third area are formed integrally.

20

Fig. 1

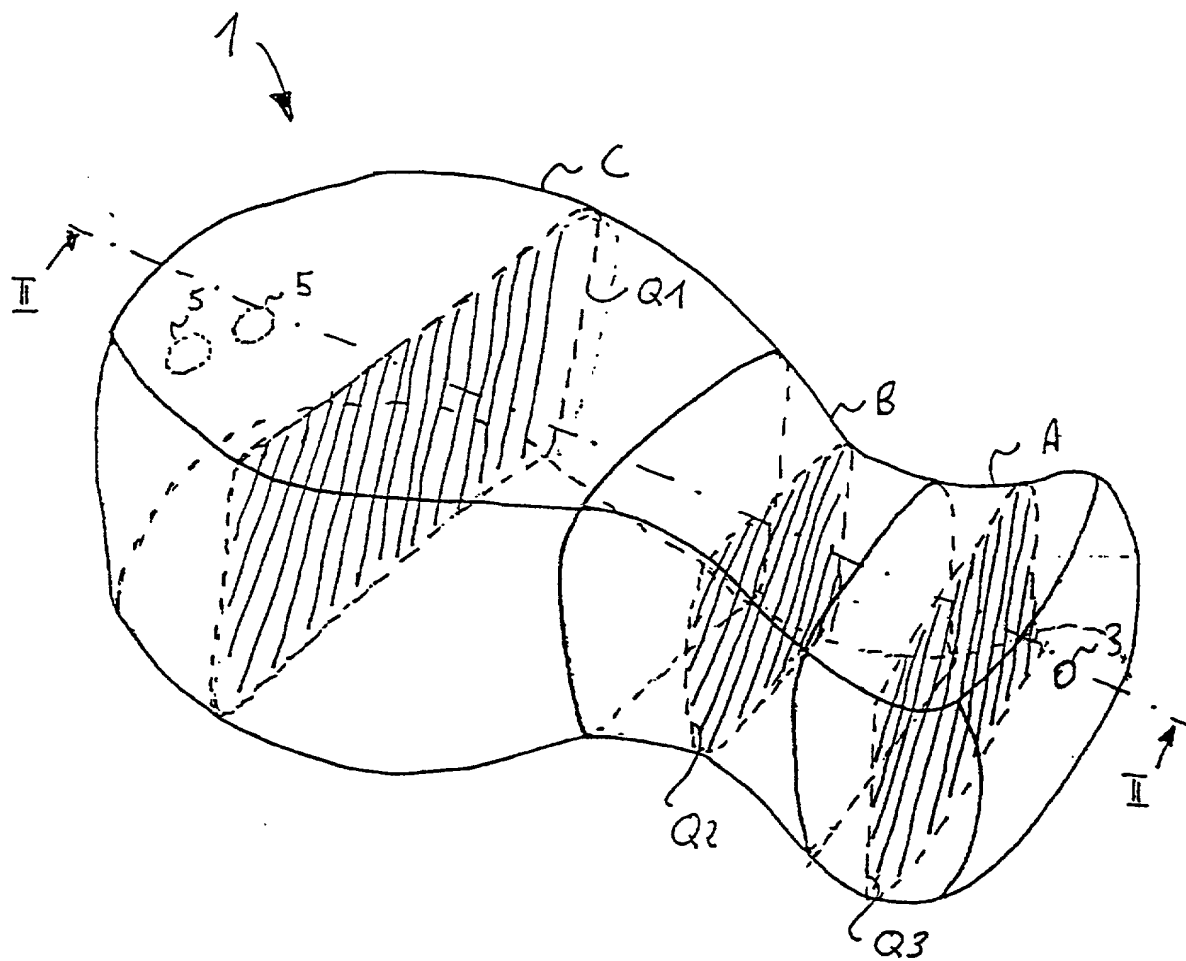
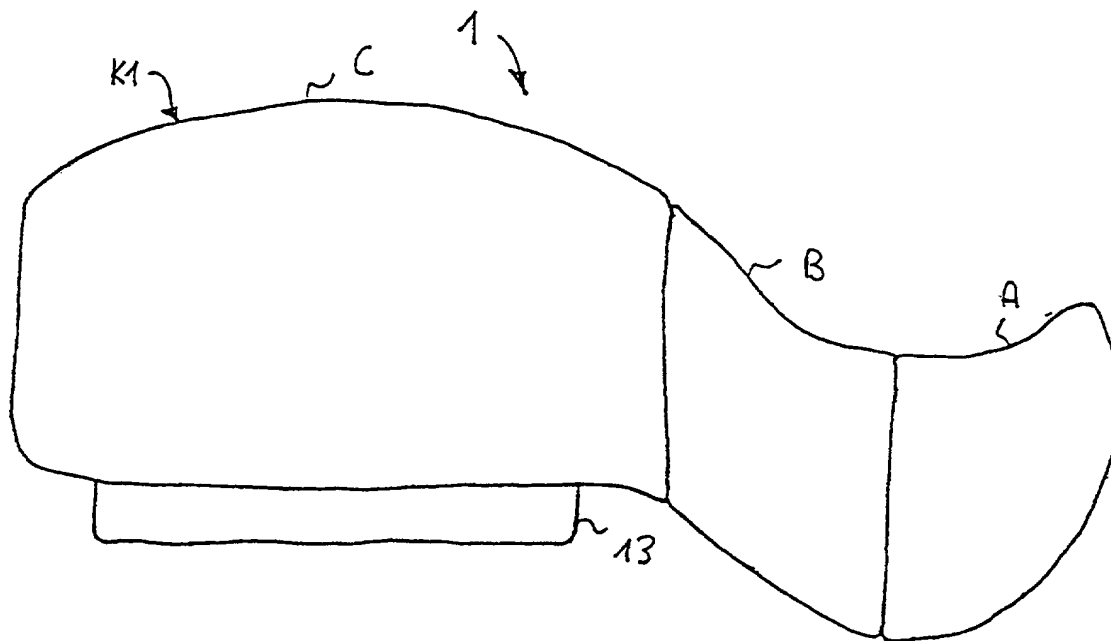


Fig. 2



09/996/21

Fig. 3

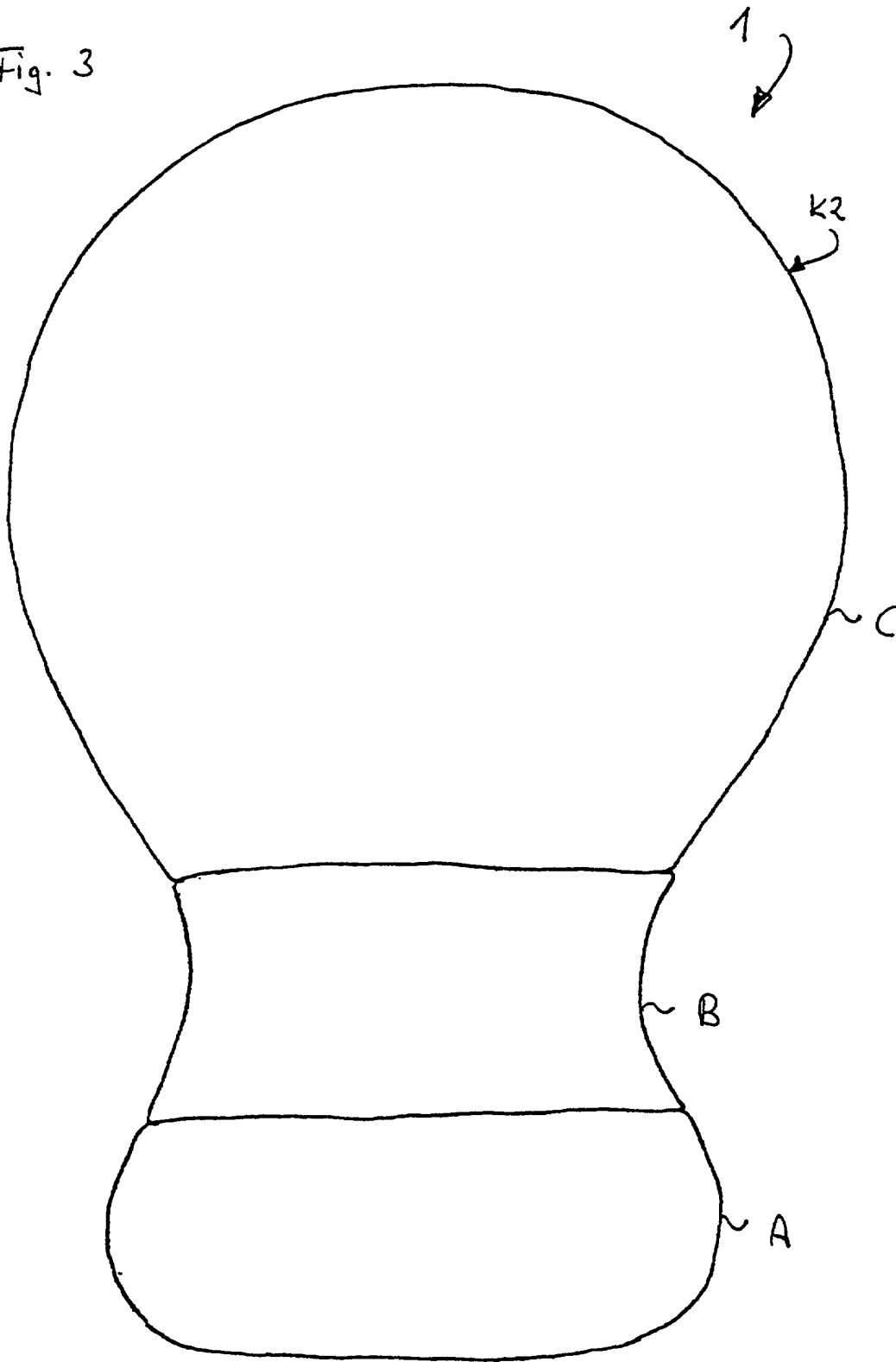
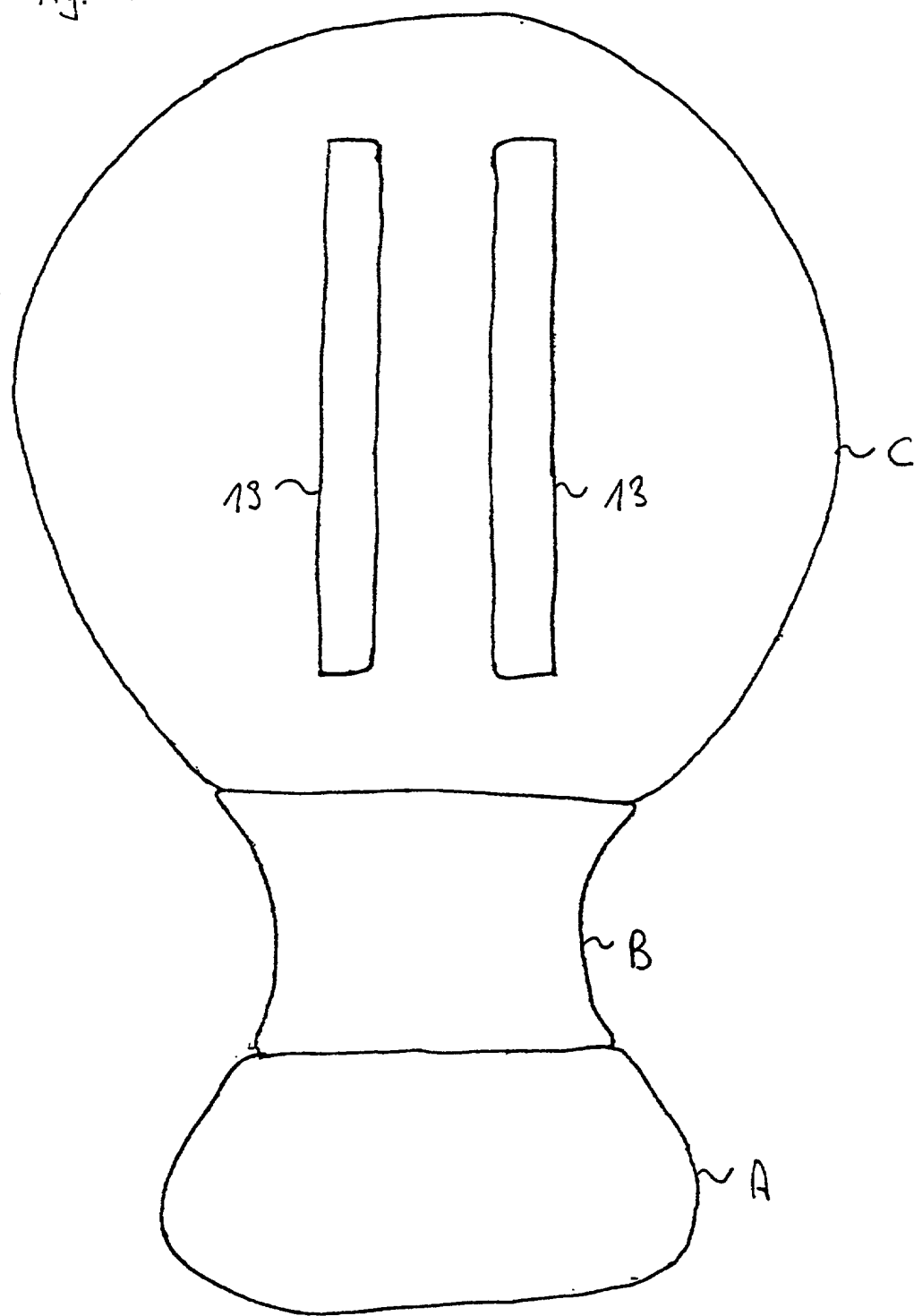




Fig. 4



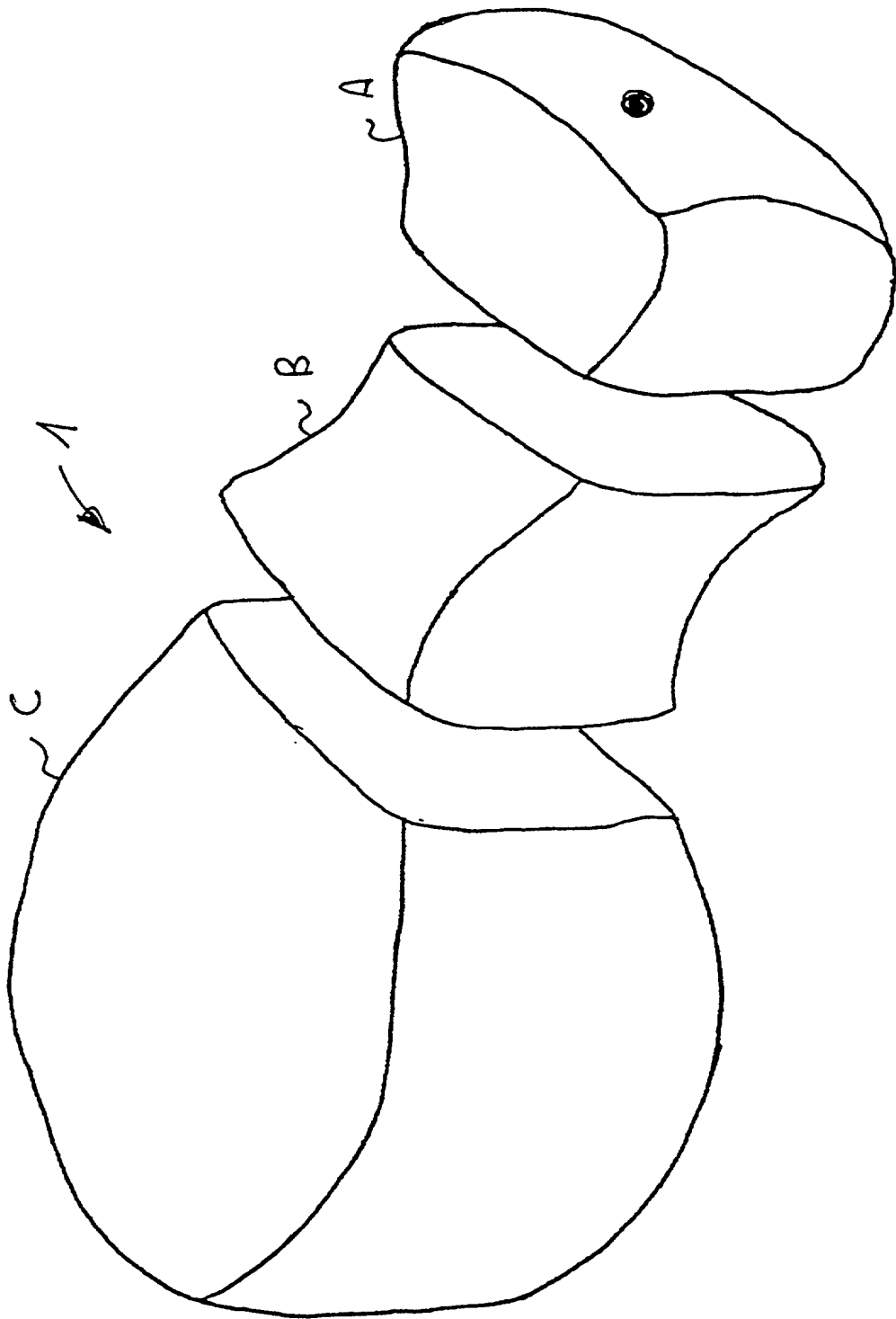
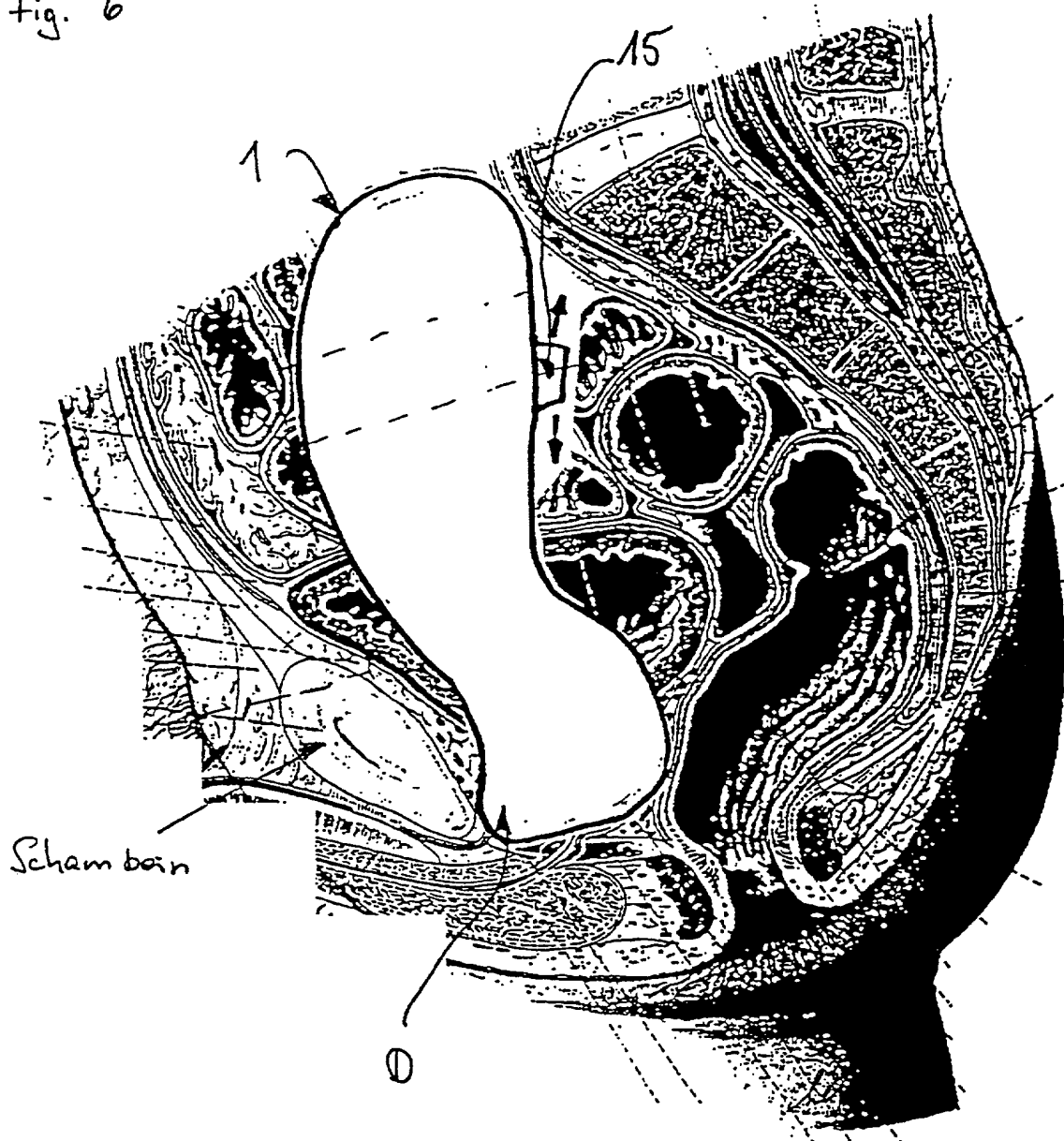


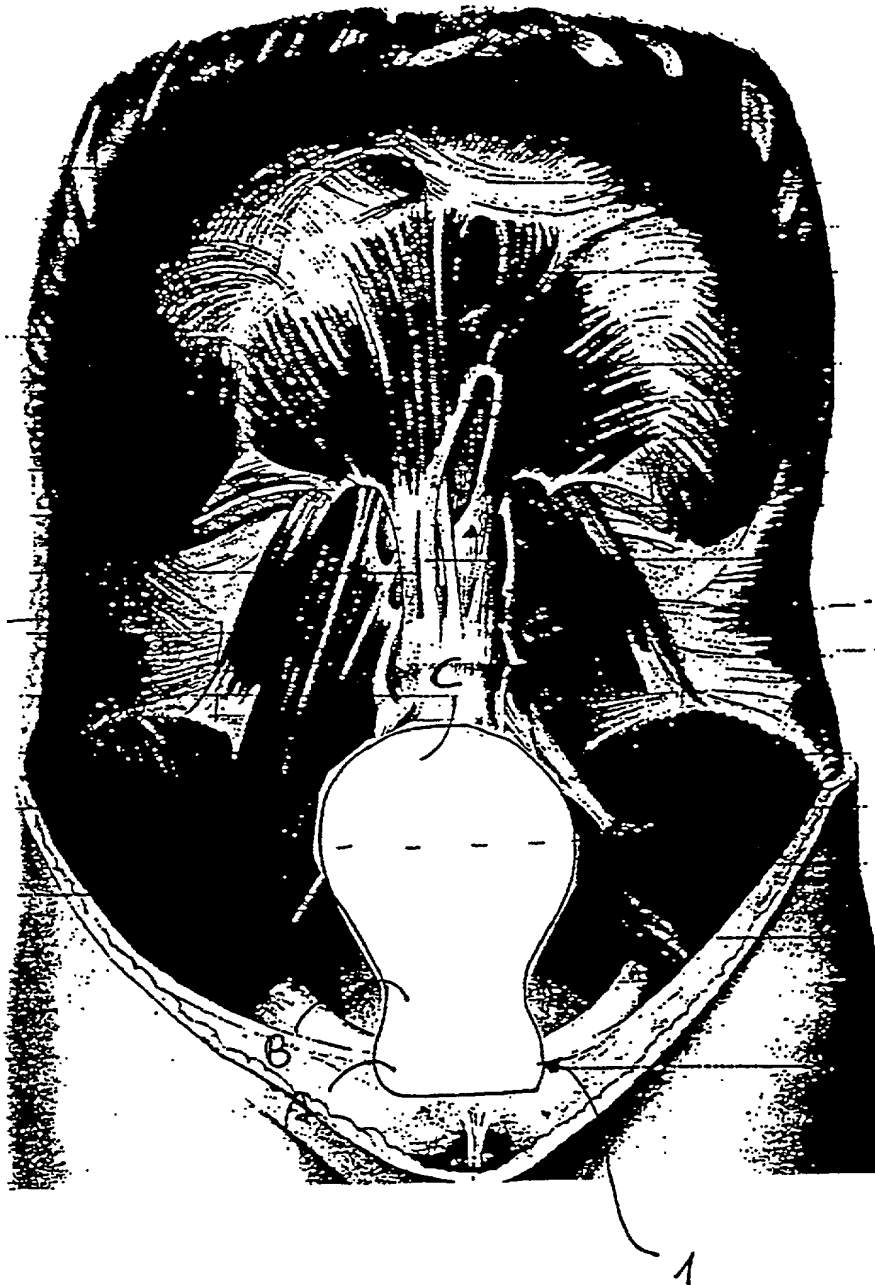
Fig. 5

Fig. 6



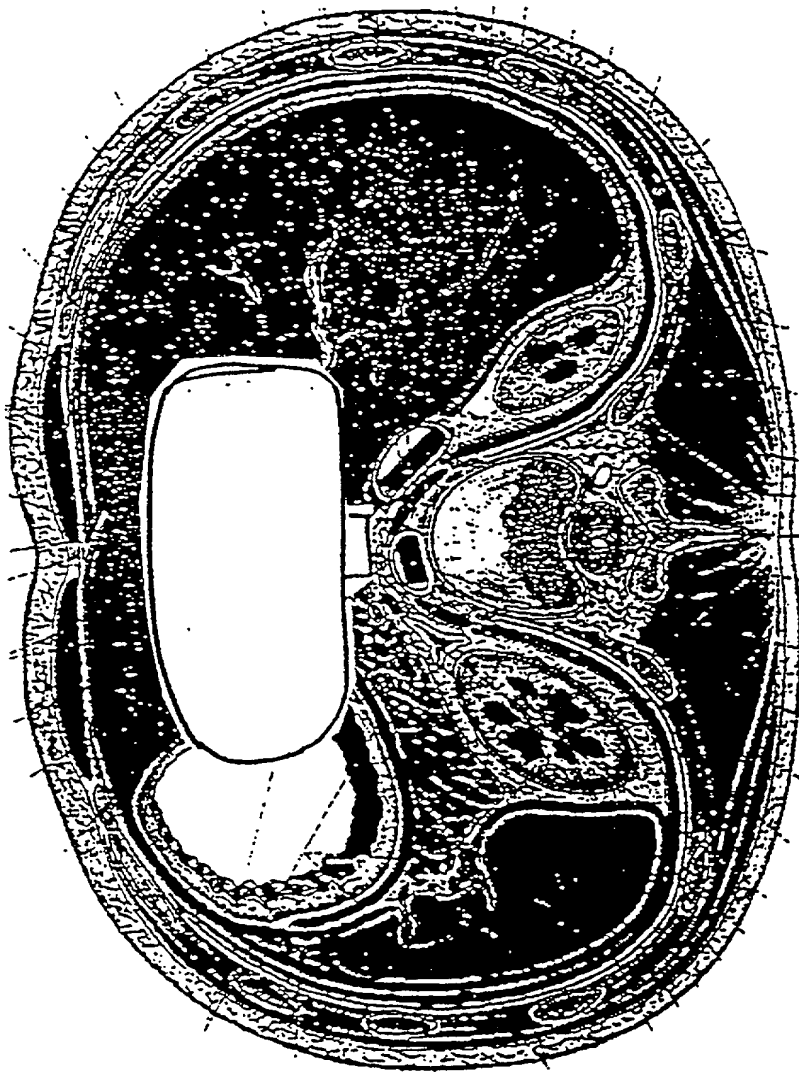
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Fig. 7



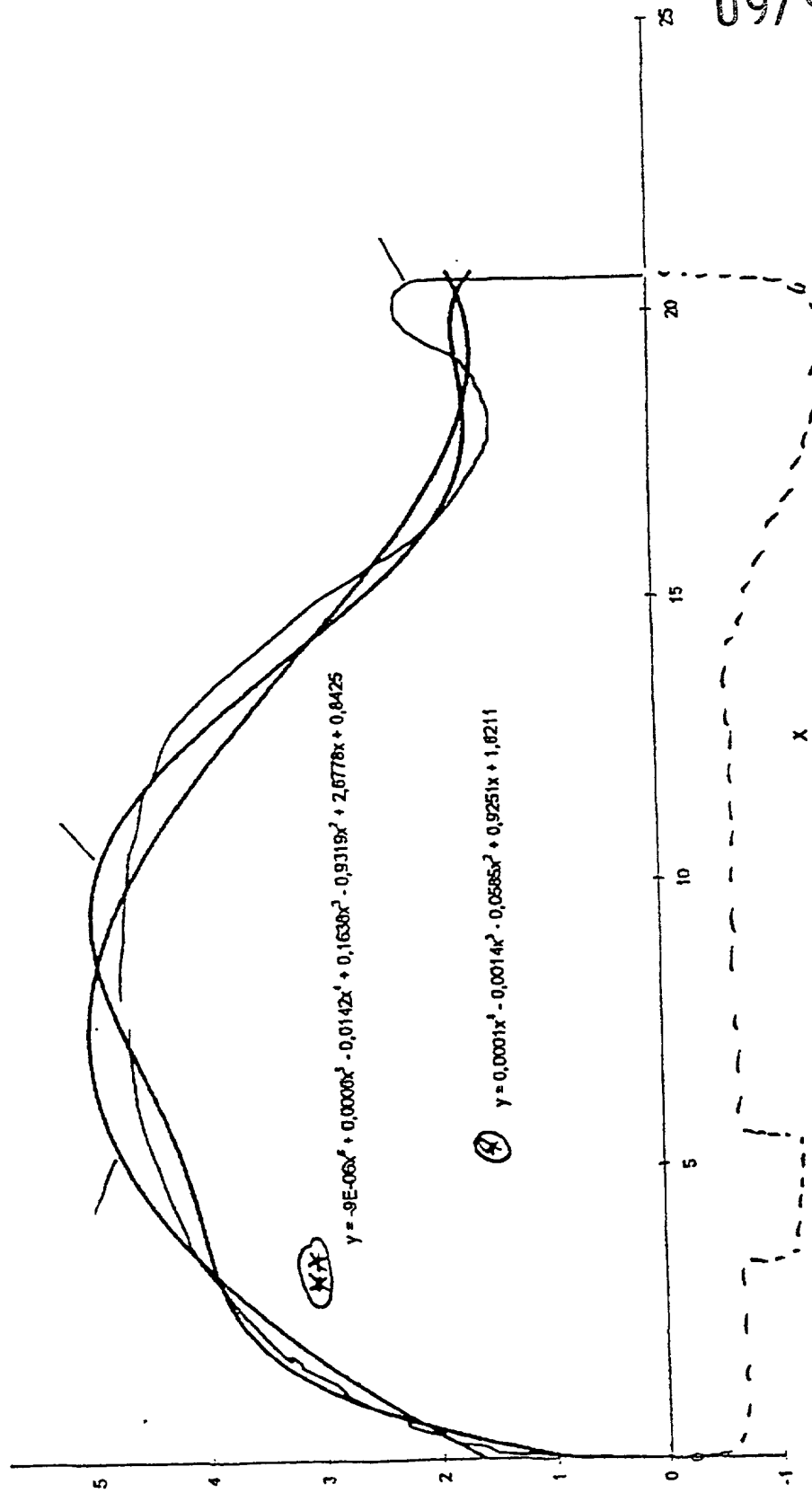
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Fig. 8



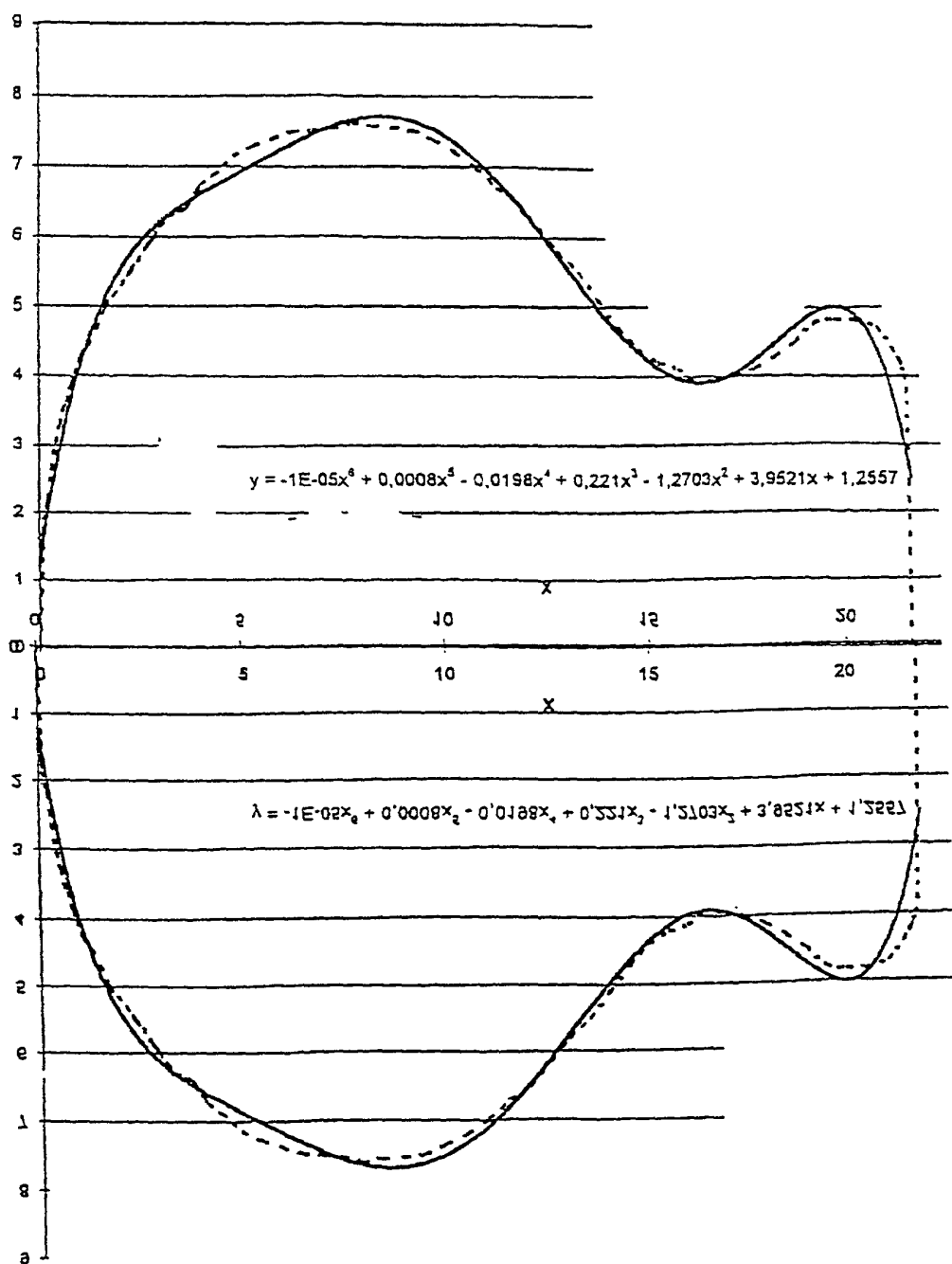
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Fig. 9



09/936721

Fig. 10



09/936721

Table 1. Demographic characteristics of the study population	
Age (years)	65.0 ± 1.5
Gender	Male 50.0%
Education (years)	12.0 ± 1.0
Marital status	Married 70.0%
Income (€)	1500.0 ± 200.0
Health status	Good 60.0%
Smoking status	Smoker 30.0%
Alcohol consumption	Alcohol 20.0%
Physical activity	Active 40.0%
Comorbidities	Hypertension 45.0%
Diabetes 15.0%	
Cholesterol 35.0%	
Heart disease 25.0%	
Stroke 10.0%	
Other 15.0%	
Medication	Medication 55.0%
Healthcare utilization	Healthcare 65.0%
Quality of life	Quality of life 75.0%
Life expectancy	Life expectancy 80.0%
Healthcare costs	Healthcare costs 100.0%
Healthcare quality	Healthcare quality 90.0%
Healthcare access	Healthcare access 85.0%
Healthcare equity	Healthcare equity 80.0%
Healthcare sustainability	Healthcare sustainability 75.0%
Healthcare innovation	Healthcare innovation 70.0%
Healthcare leadership	Healthcare leadership 65.0%
Healthcare governance	Healthcare governance 60.0%
Healthcare accountability	Healthcare accountability 55.0%
Healthcare transparency	Healthcare transparency 50.0%
Healthcare integrity	Healthcare integrity 45.0%
Healthcare justice	Healthcare justice 40.0%
Healthcare beneficence	Healthcare beneficence 35.0%
Healthcare non-maleficence	Healthcare non-maleficence 30.0%
Healthcare autonomy	Healthcare autonomy 25.0%
Healthcare respect for persons	Healthcare respect for persons 20.0%
Healthcare confidentiality	Healthcare confidentiality 15.0%
Healthcare privacy	Healthcare privacy 10.0%
Healthcare security	Healthcare security 5.0%
Healthcare safety	Healthcare safety 0.0%

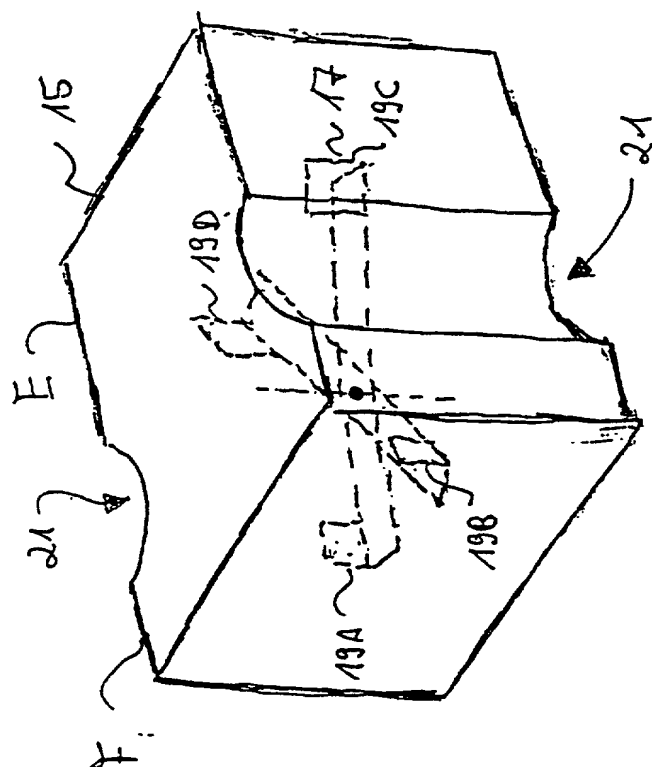
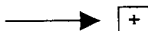


Fig. 11



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<b>DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)</b>  <input type="checkbox"/> Declaration Submitted with Initial Filing    OR <input checked="" type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)	<b>Attorney Docket Number</b>	HAMMON-002
	<b>First Named Inventor</b>	Helmut Wassermann, et al.
	<b>COMPLETE IF KNOWN</b>	
	<b>Application Number</b>	09/936,721 ✓
	<b>Filing Date</b>	September 17, 2001 ✓
	<b>Group Art Unit</b>	N/A
	<b>Examiner Name</b>	Not Yet Assigned

**As a below named inventor, I hereby declare that:**

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

ARTIFICIAL URINARY DIVERSION SYSTEM

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) March 17, 2000 ✓ as United States Application Number or PCT International

Application No. PCT/EP00/02407 ✓ and was amended on (MM/DD/YYYY) May 2, 2001 & June 5, 2001 (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
199 12 218.0 ✓	GERMANY ✓	3/18/1999	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
199 12 472.8 ✓	GERMANY ✓	3/19/1999	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

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## DECLARATION — Utility or Design Patent Application

**POWER OF ATTORNEY** As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith Customer Number 000530

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

**NAME OF SOLE OR FIRST INVENTOR:**



A petition has been filed for this unsigned inventor

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(first and middle [if any])

Helmut

Family Name  
or Surname

Wassermann

Inventor's  
Signature

München

Date

NOV 16 / 2001

Residence: City

State

Country

Germany

Citizenship

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Mailing  
Address:

Struwelpeterstrasse 5B

City

München

State

ZIP

D-81739

Country

Germany

**NAME OF SECOND INVENTOR:**



A petition has been filed for this unsigned inventor

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(first and middle [if any])

Dieter

Family Name  
or Surname

Jocham

Inventor's  
Signature

Lübeck

Date

26.11.2001

Residence: City

State

Country

Germany

Citizenship

Germany

Mailing  
Address:

Zwinglistrasse 1

City

Lübeck

State

ZIP

D-23568

Country

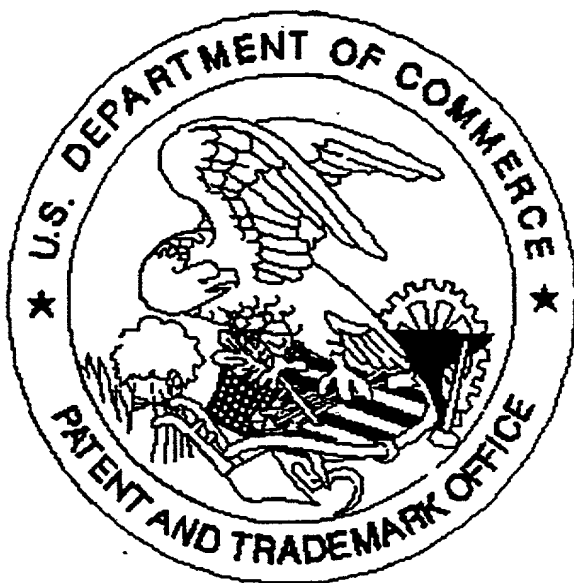
Germany



Additional inventors are being named on the

supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto

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